

Rejection of Claims 6, 8, 9, and 19-23 Under 35 U.S.C. § 112, First Paragraph

The Office newly rejected claims 6, 8, 9, and 19-23 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants respectfully traverse that rejection.

The Office stated that “claims 8, 20, 21, and 22 have all been amended to include differentiated stem cells.” Action at page 2, item no. 3. Applicants respectfully provide the following clarification. The language “differentiated stem cells” is not recited in any of claims 8, 20, or 21. Independent claim 8 is directed to “[a] method of identifying the differentiation state of a test stem cell, test stem cell tissue, or test stem cell nucleus.” The method comprises multiple elements, including “obtaining a differentiation state-specific DNA methylation pattern for one or more stem cell, stem cell tissue, or stem cell nucleus of known differentiation state.” Claim 20 depends from claim 8 and recites “the differentiation state-specific DNA methylation pattern for one or more stem cell, stem cell tissue, or stem cell nucleus of known differentiation state is differentiated.” Claim 21 depends from claim 8 and recites “the differentiation state-specific DNA methylation pattern for one or more stem cell, stem cell tissue, or stem cell nucleus of known differentiation state is undifferentiated.” It is clear that those three claims do not recite “differentiated stem cells,” but rather encompass “one or more stem cell, stem cell tissue, stem cell nucleus of known differentiation state.” In certain embodiments, the known differentiation state is differentiated. In certain other embodiments, the known differentiation state is undifferentiated. Accordingly, since the claims do not recite “differentiated stem cells,” Applicants respectfully request reconsideration and withdrawal of the rejection of claims 8, 20, 21, and claims 6, 9, and 19, which depend from claim 8, under § 112, paragraph 1, as allegedly failing to comply with the enablement requirement.

While Applicants believe that this explanation is fully dispositive, should the Office find otherwise, Applicants respectfully request consideration of the arguments presented below, which, while addressing the rejection of claims 22 and 23, would be similarly applicable to claims 8, 20, and 21. Independent claim 22 recites “differentiated embryonic stem cell” and “differentiated trophoblast stem cell.” Claim 23 depends from claim 22.

The Office alleged that,

by definition a stem cell is an undifferentiated cell with certain functional capabilities (Potten et al., Development (1990) Volume 110, pages 1001-1020, especially page 1002, paragraph bridging right and left column) [(“Potten”)]. The specification does not define stem cells as anything different from what is in the prior art. Thus, it is unclear how one of ordinary skill in the art is to obtain the methylation pattern of a differentiated stem cell, since differentiated stem cells do not exist by definition.

Action at pages 2-3, item no. 3. Applicants respectfully disagree.

First, Applicants note that Potten does not define stem cells for the art as a whole. Indeed, Potten states that “**we would define the stem cells as undifferentiated cells** capable of, (a) proliferation, (b) selfmaintenance, (c) the production of a large number differentiated, functional progeny, (d) regenerating the tissue after injury , and (e) flexibility in the use of these options. . . .” Potten at page 1002 (emphasis added). Thus, Potten indicates that they have merely described their definition of stem cells. Moreover, that definition expressly contemplates “flexibility” thereby acknowledging alternative definitions. Thus, it is not the case that “differentiated stem cells do not exist by definition.”

In addition, the basis for the rejection is unclear given the Office’s express acknowledgement of the support for “differentiated stem cells” throughout the specification, for example, at “page 12, page 16, Figure 4 and Figure 5.” Action at page 3. The Office alleged that, “given that the prior art demonstrates that the commonly accepted meaning of stem cell is

an undifferentiated cell, it is unclear what is being labeled as a differentiated stem cell.

Furthermore, the specification does not teach how to create what is labeled as a differentiated stem cell, so that one of skill in the art may recreate the data in Figure 4 and 5.” *Id.* Applicants respectfully disagree.

Contrary to the Office’s position, the specification provides more than ample guidance for “creat[ing] what is labeled as a differentiated stem cell, so that one of skill in the art may recreate the data in Figure 4 and 5.” The specification teaches, for example, that

if the production of differentiated ES cells is intended, undifferentiated ES cells may be cultured after random methylation of genes thereof. The cultivation may be carried out in a medium, e.g., commonly used RPMI1640, DMEM, MEM or such a medium supplemented with bovine serum albumin, etc., according to conventional animal cell culture techniques. Subsequently, the resultant cells are subjected to random demethylation. Then, information on methylation patterns is analyzed as described above. Using the analysis results as an indicator, those cells in which gene 2 is methylated and gene 4 is demethylated are screened for and isolated. Thus the cell of interest can be obtained.

Specification at page 12, last line, through page 13, first paragraph.

Additional guidance for the preparation of differentiated stem cells is also provided, for example, in Example 1, at page 19. Example 1 is a working example that teaches analysis of methylation patterns of several cell types including embryonic stem cells and trophoblast stem cells, using an RLGS technique. At page 19, first full paragraph, the specification teaches that

[t]hose positions at which the pattern of detected spot differs depending on types of cells or tissues were given identification numbers (Nos. 1-167 in Fig. 3). Examples of some spot patterns detected at those positions are shown in Fig. 4. In Fig. 4, spot #79 is specific to embryonic stem cell and not found in other cells or tissues. Spot #98 is specific to trophoblast stem cell. . . . Spot #99 is observed in brain and differentiated trophoblast cell. . . .

The second full paragraph at page 19 explains that “[a] schematic drawing of cell/tissue-specific methylation patterns on the above-mentioned 167 spots is given in Fig. 5.” A detailed explanation of how to analyze the data shown schematically in Fig. 5, including how to identify

undifferentiated embryonic stem cells, differentiated embryonic stem cells, undifferentiated trophoblast stem cells, and differentiated trophoblast stem cells, is provided at page 16, first full paragraph, through page 17, first paragraph.

Thus, the specification clearly provides more than ample guidance for “creat[ing] what is labeled as a differentiated stem cell, so that one of skill in the art may recreate the data in Figure 4 and 5.” As discussed above, the specification teaches how to produce differentiated ES cells by cultivating undifferentiated ES cells in “commonly used” media “according to conventional animal cell culture techniques.” One skilled in the art would be familiar with such “commonly used” media and such “conventional animal cell culture techniques.” In addition, as discussed above, the specification provides a detailed example that teaches how to produce and analyze the data shown in Figures 4 and 5.

Therefore, it would not require undue experimentation for one skilled in the art to prepare and use differentiated stem cells according to the method of claim 22. To the extent the Office finds that claims 8, 20, and 21 include “differentiated stem cells,” Applicants assert that it would similarly not require undue experimentation for one skilled in the art to prepare and use alleged “differentiated stem cells” according to the methods of claims 8, 20, and 21. Accordingly, claims 8, 20, 21, and 22 are fully enabled by the specification. Claims 6, 9, and 19 depend from claim 8, and claim 23 depends from claim 22. Thus, claims 6, 9, 19, and 23 are also fully enabled by the specification. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 6, 8, 9, and 19-23 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

CONCLUSION

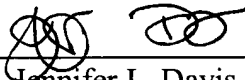
In view of the foregoing remarks and arguments, Applicants respectfully assert that the application is in condition for allowance and request the timely issuance of a Notice of Allowance. If the Examiner does not consider the claims allowable, the undersigned requests that, prior to taking action, the Examiner call her at (650) 849-6749 to set up an interview.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: November 20, 2006

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